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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,206	10/09/2003	Patricia Rao	TLN-021CP	5073
959	7590	04/04/2006	EXAMINER	
LAHIVE & COCKFIELD			LI, QIAN JANICE	
28 STATE STREET			ART UNIT	
BOSTON, MA 02109			PAPER NUMBER	

1633

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/684,206	Applicant(s) RAO ET AL.	
	Examiner Q. Janice Li, M.D.	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1-20 are drawn to a method for treating a subject having a condition comprising administering to the subject an agent that modulates the expression or activity of a molecule. Classification is to be determined depending on the type of the agent.
- II. Claims 21-28 are drawn to a method for identifying or screening compounds that modulate a molecule selected from the group consisting of PTGER2, TGFb1, Jagged-1, etc. Classification is to be determined depending on the nature of the assay.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II and I are independent or distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different methods are directed to different process for modulating T cells in a subject or screening for compounds in vitro. The different methods have different method steps, use different protocols, different modes of operation, and have distinct technical considerations.

It is noted group I encompasses multiple inventions directed to a method of modulating a distinct molecule as recited in claims 1 and 2, i.e. each molecule is structural distinct from the other, has a different mode of operation, and does not overlap in a structured search. These molecules do not share a substantial structural feature essential to a common utility. In addition, a person of ordinary skill in that art would not envision one in view of the other. Further, the agent that modulate the expression or activity of a molecule encompasses structurally distinct compounds, which may be patentably distinct. Thus, upon election of group I, further election of a specific molecule subject to modulation and a specific agent is required. Please note that this is an election of invention, not a species election.

It is also noted group II encompasses multiple inventions directed to a method of identifying compounds that modulating a distinct molecule as recited in claims 21 and 22, i.e. each molecule is structural distinct from the other, has a different mode of operation, does not overlap in a structured search, and cannot be used together in a screening assay. Thus, upon election of group II, further election of a specific molecule subject to modulation is required. Please note that this is an election of invention, not a species election.

The differences of the Inventions I and II are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all

the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention. Upon election of an invention for examination in this application, further election of a species is necessary. The species is defined as a combination of the following factors:

If one of the inventions in group I is elected, identify:

- a. a specific condition that would benefit from balancing regulatory and effector T cells, such as recited in claims 8 and 10;
- b. whether the molecule is a gene or a polypeptide, upregulated or downregulated, or unchanged.

If one of the inventions in group II is elected, identify

- a. a specific molecule to be modulated, and the nature of the molecule, a protein or a nucleic acid;
- b. whether the assay is carried out in vitro or in vivo;
- c. whether the assay involves a cell or cell free.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of a, b, and c, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-20 are generic, i.e. no single claim is drawn to a particular species.

Each of the listed species is directed to structurally and functionally distinct, and not overlapped in structure search. Thus, a search and examination of anything more

than one of such together for patentability would be unduly burdensome to the examiner.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be

traversed (37 CFR 1.143), and a listing of all claims readable thereon, including any claims subsequently added.

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **William Phillips**, whose telephone number is (571) 272-0548.

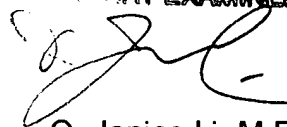
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at **800-**

786-9199.

Q. JANICE LI, M.D.
PRIMARY EXAMINER



Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
March 31, 2006